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Total No. of Pages : 02

Total No. of Questions : 10

**B.Pharma (2011 to 2016) (Sem.-8)**  
**PHARMACEUTICS-IX (DOSAGE FORM DESIGN)**  
**Subject Code : BPHM-801**

Time : 3 Hrs.

Max. Marks : 80

**INSTRUCTIONS TO CANDIDATES :**

1. **SECTION-A** is **COMPULSORY** consisting of **FIFTEEN** questions carrying **TWO** marks each.
2. **SECTION-B** contains **FIVE** questions carrying **FIVE** marks each and students have to attempt any **FOUR** questions.
3. **SECTION-C** contains **FOUR** questions carrying **TEN** marks each and students have to attempt any **THREE** questions.

**SECTION-A****1. Answer briefly :**

- a) What is meant by pharmaceutical equivalent?
- b) What is retrospective validation?
- c) What is racemization? Give two examples.
- d) Give two examples of BCS III drugs.
- e) What should be the disintegration time of dispersible tablets IP?
- f) Mention the stability testing conditions for Zone II.
- g) Propyl gallate and EDTA are used for which purposes?
- h) Give examples of two drugs that are formulated in micronized state.
- i) Mention the methods that can be used for enhancing the solubility of poorly water soluble drugs.
- j) Differentiate between controlled and delayed release.



- k) Why is DOSS added to dissolution media?
- l) What is absolute availability?
- m) What is the difference between excretion and elimination?
- n) Enumerate different types of particle diameters.
- o) What is meant by sedimentation volume of suspensions?

### SECTION-B

- 2. Write briefly about the impact of particle size and shape in influencing the stability of suspensions.
- 3. Giving examples of prodrugs that have proven advantage over their parent molecular forms, explain the reasons thereof.
- 4. What is BCS? Briefly describe the different classes of drugs giving examples.
- 5. Give examples of drugs that are highly prone to oxidation and suggest methods to make them stable.
- 6. Write a brief note on Quality Audit.

### SECTION-C

- 7. Enlist the physicochemical properties of drugs that are evaluated during preformulation phase. Discuss the importance of particle size, shape and density in influencing dosage form development.
- 8. What is validation? Explain the different types of validations and mention the conditions for which they are carried out.
- 9. Discuss the key features of a Bioequivalence trial. Discuss the ICH requirements for establishing Bioequivalence of drug products.
- 10. Discuss the IVIVC requirements according to ICH guidelines.

**NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.**